Notice of Allowability	Application No.	Applicant(s)	_
	10/630,384	SCHAUDIES ET AL.	
	Examiner	Art Unit	_
	Jeffrey Fredman	1637	
The MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.31	is (OR REMAINS) CLOSED in or other appropriate community IGHTS. This application is s	n this application. If not included unication will be mailed in due course. THIS	/e
1. This communication is responsive to <u>12/19/2005</u> .		·	
2. X The allowed claim(s) is/are 16-63,80-124,136-142 and 14	<u>4-147</u> .		
 Acknowledgment is made of a claim for foreign priority unally All b) Some* c) None of the: Certified copies of the priority documents have Certified copies of the priority documents have Copies of the certified copies of the priority documents have Moreover the priority documents have	e been received. e been received in Applicatio	on No	
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDON! THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		a reply complying with the requirements	
4. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give			
 5. CORRECTED DRAWINGS (as "replacement sheets") mu (a) including changes required by the Notice of Draftsper 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR each sheet. Replacement sheet(s) should be labeled as such in 6. DEPOSIT OF and/or INFORMATION about the deposit attached Examiner's comment regarding REQUIREMENT 	son's Patent Drawing Review 's Amendment / Comment or 1.84(c)) should be written on the header according to 37 CF osit of BIOLOGICAL MATE	in the Office action of the drawings in the front (not the back) of R 1.121(d). ERIAL must be submitted. Note the	
Attachment(s) 1. Notice of References Cited (PTO-892) 2. Notice of Draftperson's Patent Drawing Review (PTO-948) 3. Information Disclosure Statements (PTO-1449 or PTO/SB/Paper No./Mail Date 4. Examiner's Comment Regarding Requirement for Deposit of Biological Material	6. ☐ Interview Si Paper No./ 08), 7. ⊠ Examiner's	formal Patent Application (PTO-152) JEFFREY FREDMAN PRIMARY EXAMINER	

Art Unit: 1637

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jamie Greene on January 20, 2006.

The application has been amended as follows:

Claims 125, 127-130 and 143 were cancelled without prejudice towards further prosecution.

The following claims were amended as shown.

- 16. A method for detecting one or more biological entities in a sample, comprising:
 - (a) combining one or more nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

(b) randomly amplifying the sample nucleic acid sequences to produce nucleic acid amplification products;

Art Unit: 1637

(c) combining the amplification products with an array of predetermined nucleic acid sequences including redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and such that at least a portion of the amplification products hybridize to the array; and

- (d) detecting amplification products that hybridize to the array.
- 32. A method for detecting one or more biological entities in a sample, comprising:
 - (a) combining one or more nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

- (b) randomly amplifying the sample nucleic acid sequences to produce nucleic acid amplification products;
- (c) combining the amplification products with an array of predetermined nucleic acid sequences including positive controls, negative controls and redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and such that at least a portion of the amplification products hybridize to the array; and
 - (d) detecting amplification products that hybridize to the array.

Art Unit: 1637

48. A method for detecting one or more biological entities in a sample, comprising:

(a) combining nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

- (b) randomly amplifying the sample nucleic acid sequences to produce nucleic acid amplification products;
- (c) combining the amplification products with an array of predetermined nucleic acid sequences having a known spatial arrangement or relationship to each other and further comprising redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and such that at least a portion of the amplification products hybridize to the array; and
 - (d) detecting amplification products that hybridize to the array.
- 80. A method for detecting one or more biological entities in a sample, comprising:
 - (a) combining nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

Art Unit: 1637

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

- (b) randomly amplifying the sample nucleic acid sequences at each cycle of the polymerase chain reaction, to produce nucleic acid amplification products;
- (c) combining the amplification products with an array of predetermined nucleic acid sequences including redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and such that at least a portion of the amplification products hybridize to the array and wherein the redundancies on the array further comprise more than one copy of the same nucleic acid sequence; and
 - (d) detecting amplification products that hybridize to the array.
- 96. A method for detecting one or more biological entities of a plurality of preselected biological entities potentially present in a sample, comprising:
 - (a) combining nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

(b) randomly amplifying the sample nucleic acid sequences to produce nucleic acid amplification products;

Art Unit: 1637

(c) hybridizing the amplification products to an array of predetermined positions on the array in a predetermined pattern, wherein the nucleic acid seuqences at the predetermined positions characterize at least one of the plurality of preselected biological entities and wherein the array comprises redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and

- (d) detecting amplification products that hybridize to the array.
- 141. A method for detecting one or more pathogens in a sample, wherein the pathogens are used for the production of biological weapons for terrorism or battlefield use, comprising:
 - (a) combining one or more nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently

randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products;

- (b) randomly amplifying the sample nucleic acid sequences to produce nucleic acid amplification products;
- (c) combining the amplification products with an array of predetermined nucleic acid sequences including redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and such that at least a portion of the amplification products hybridize to the array; and

Art Unit: 1637

(d) detecting amplification products that hybridize to the array.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The claimed 2. invention is drawn to a combination of randomized PCR followed by hybridization to an array. As discussed in the previous action, Peng teaches randomized PCR and Beattie teaches hybridization detection on an array. The claims as amended are allowable since they all have the requirement that there are redundancies which comprise multiple distinct nucleic acids from the same target entity and in view of the declaration filed 12/19/05 by Paul Schaudies. The claim amendment could be met by other prior art which teaches the use of multiple nucleic acids for targeting in hybridization. However, the declaration shows the significant result, which is unexpected by the cited prior art of Beattie and Peng, that increasing the redundancy provides a significant increase in the confidence of detection. The claims are all now commensurate in scope with this result since all of the claims incorporate the requirement that multiple redundant nucleic acids from the target are present on the array. Therefore, in balancing the suggestive power of the references against the new limitations in the claims and the evidence in the declaration, the claims are novel and unobvious over the cited prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1637

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffréy Fredman Primary Examiner Art Unit 1637